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| APPLICATION NO.                                                                         | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.                  | CONFIRMATION NO. |
|-----------------------------------------------------------------------------------------|-------------|----------------------|--------------------------------------|------------------|
| 10/550,163                                                                              | 11/01/2005  | Myong-Ki Jun         | 20506/0203371-US0                    | 5320             |
| 7278 7590 03/07/2007<br>DARBY & DARBY P.C.<br>P. O. BOX 5257<br>NEW YORK, NY 10150-5257 |             |                      | EXAMINER<br>PAPAPIETRO, JACQUELINE M |                  |
|                                                                                         |             |                      | ART UNIT                             | PAPER NUMBER     |
|                                                                                         |             |                      | 3739                                 |                  |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|----------------------------------------|------------|---------------|
| 3 MONTHS                               | 03/07/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|                              |                                   |                               |  |
|------------------------------|-----------------------------------|-------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/550,163     | Applicant(s)<br>JUN, MYONG-KI |  |
|                              | Examiner<br>Jacqueline Papapietro | Art Unit<br>3739              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 January 2006 and 20 September 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-9,15-17 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-9,15-17 and 21-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 September 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                                |                                                                                         |
|--------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                           | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/20/05</u> | 6) <input type="checkbox"/> Other: _____                                                |

**DETAILED ACTION*****Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the power source and "porous metal sintered body layer" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

The disclosure is objected to because of the following informalities: There are numerous mistakes throughout the specification, such as the punctuation "more particularly to, an electrode" in line 5 of page 1, the language "is operated as an insulator, namely an obstacle to enlargement" in lines 17-18 of page 1, "a liver cancer" in line 23 of page 6, and "an spearhead" in line 21 of page 7.

Appropriate correction is required.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The use of the trademark TEFLON has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### ***Claim Objections***

Claims 1, 3-9, 15-17, and 21-28 are objected to because of the following informalities: The recitation "resulting to cool" in line 9 of claim 1 and line 8 of claim 21 is idiomatic English. Claims 3, 7, 15-17, and 22 recite "inserted onto," which is also idiomatic English. Claim 6 recites, "spear head" and "spearhead" in line 2; Applicant should be consistent. There is an extraneous "[a]" in line 5 of claim 9. Claims 7 and 15-17 recite "alternately installing" in the fifth line of each claim, which is unclear. Examiner

suggests replacing this recitation with "aligning." Claim 23 recites "different power" in line 3 of the claim. This language is unclear; for examination purposes, "different power" has been interpreted to mean in a bipolar configuration, as explained in the specification (page 12). Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-9, 15-17, and 21-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "configured to externally discharge heat-exchanged refrigerants from the living tissue through a gap" in lines 10-11. The language is unclear and confusing.

Claim 3 recites "the outside surface except the second non-insulation area" in lines 4-5 of the claim. The language is unclear and confusing. The same confusing language is found in lines 4-5 of claim 22.

Claim 3 recites "the gap" in line 6 of the claim. It is unclear if this is meant to refer to the gap of line 11 in claim 1, or the predetermined gap of line 3 in claim 3. The same lack of clarity exists in line 6 of claim 4, and in line 6 of claim 22, and line 5 of claim 23.

Claims 1, 7-9, and 15-17 recite the limitation "the first hole." There is insufficient antecedent basis for this limitation in the claim, but proper antecedent basis for "the at least one first hole."

Claim 1 recites the limitation "the outside surface of the first non-insulation area" in lines 12 and 17 of the claim. There is insufficient antecedent basis for this limitation in the claim. The same lack of antecedent basis occurs in line 2 of claim 7, line 2 of claim 9, line 2 of claim 15, line 2 of claim 16, and line 2 of claim 17.

Claim 3 recites the limitation "the outside surface" in line 4 of the claim. There is insufficient antecedent basis for this limitation in the claim. It is unclear to which outside surface it is meant to refer. The same lack of clarity is found in lines 3-4 of claim 15, lines 3-4 of claim 16, and lines 3-4 of claim 17.

Claim 3 recites the limitation "the outside surface of the second non-insulation area" in line 7 of the claim. There is insufficient antecedent basis for this limitation in the claim. The same lack of antecedent basis is found in line 7 of claim 22.

Claim 8 recites the limitation "compression units" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim, as it is unclear what the compression units are.

Claim 21 recites "operable to externally discharge a portion of the refrigerants supplied through the refrigerant tube into the living tissue in contact with the closed tip," which is confusing and unclear. The refrigerants are not supplied into the living tissue and then discharged through the gap between the refrigerant tube and the hollow electrode.

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Claim 26 recites, "proceeding a radio-frequency ablation" and "relatively much" in line 4 of the claim. This is idiomatic English.

Claim 26 recites the limitation "the outside" in line 5 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the relationship between the compression units and the hollow tube. It is unclear as what exactly the compression units are and how they are structurally a part of the hollow tube.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 6, 7, 15, 21, 22, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ni et al (US 6514251 B1) in view of Schwartz et al (US 6969373 B2).

Regarding claims 1, 3, 21, and 22, Ni discloses an electrode for an electro-surgical operation device, comprising: a hollow electrode (49, Fig 6) formed in a hollow tube shape extending from a closed tip (see Fig 6); a first non-insulation area formed to a predetermined length from the closed tip (column 3 lines 44-46); a first insulation area formed on an outside surface of the hollow electrode beginning a predetermined length from the closed tip (as implied in column 3 lines 44-46); a refrigerant tube (defined as 28 in Figs 3 and 4), having a smaller diameter than a diameter of the hollow electrode, inserted into the hollow electrode (see Fig 6), the refrigerant tube capable of being configured to supply refrigerants (i.e. 0.9% saturated saline solution, column 3 lines 16-21) into the hollow electrode for cooling living tissue in contact with the closed tip and/or the hollow electrode, and further configured to externally discharge heat-exchanged refrigerants (see Fig 8) from the closed tip through a gap between the refrigerant tube and the hollow electrode (channel 27, Fig 3); and at least one first hole (or refrigerant discharging mechanism) formed on the outside surface of the first non-insulation area (shown near the tip in Fig 6); the first hole operable to externally discharge a portion of the supplied refrigerants supplied through the refrigerant tube into the living tissue in contact with the closed tip and/or the hollow electrode (as shown by the arrows running through the holes). Ni discloses the device further comprising: a saline solution pipe (33,



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Fig 3) inserted onto the outside surface of the hollow electrode with a predetermined gap (33), and having a second non-insulation area at another predetermined length toward the closed tip (any non-insulation area on the electrode that has not been defined as the first non-insulation area) and a second insulation area on the outside surface except the second non-insulation area (any insulation area not defined as the first insulation area); the saline solution pipe operable to infuse a saline solution through the gap, and discharge the saline solution through at least one second hole (35) formed on the outside surface of the second non-insulation area (column 4 lines 2-7). Ni does not disclose flow control mechanism formed on the outside surface of the first non-insulation area.

Schwartz teaches a hollow catheter with a plurality of holes (66, Fig 11) for injecting a solution into tissue in a predetermined cloud pattern (column 4 lines 31-34). Schwartz teaches a flow control mechanism (76, Fig 11) formed on the outside surface of the catheter in the area of the holes, and operable to act as a discharge resistance to the fluids discharged from the first hole, so as to control a flow of the fluid (column 4 lines 52-58). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the flow control mechanism as taught by Schwartz in the invention of Ni in order to better control the cloud pattern of the refrigerant in the tissue to more effectively ablate the tissue.

Regarding claim 6, Ni in view of Schwartz discloses the electrode of claim 1, wherein the closed tip of the hollow electrode (shown as 29 in Fig 3 if Ni) is a conductive

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spearhead (the closed tapered tip of Ni is interpreted as a spearhead), and the hollow electrode and the spearhead are incorporated with each other (see Figs 3-7).

Regarding claims 7 and 15, Ni in view of Schwartz discloses the electrode of claims 1 and 3, wherein the flow control mechanism is a hollow tube inserted onto the outside surface of the first non-insulation area (Schwartz, Fig 11), and having a third hole on the outside surface (Schwartz, element 84, Fig 11), the flow control mechanism controlling a volume of discharged refrigerants by alternately aligning the first hole of the hollow electrode and the third hole of the hollow tube and operating as a discharge resistance to the refrigerants discharged from the first hole (Schwartz, column 17 lines 11-14, see Fig 11).

Regarding claims 26-28, the claimed method is anticipated by the normal use of the device as disclosed by Ni in view of Schwartz.

Claims 9 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ni in view Schwartz as applied to claims 1 and 21 above, and further in view of Brucker et al (US 6017338).

Ni in view of Schwartz discloses the electrode of claims 1 and 21, but does not disclose the flow control mechanism as a porous metal sintered body layer. Brucker teaches an ablation catheter (22) with a central lumen (28) for introducing fluids into the catheter. The tip of the catheter (26) is made of sintered metal which contains a plurality of randomly formed through-passages and which permits a controlled flow of fluid from the catheter (column 5 lines 30-34) and acts as a discharge resistance mechanism. It

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would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Ni in view of Schwartz by forming the flow control mechanism of porous sintered metal in order to obtain a desired discharged fluid profile in the tissue.

Claims 4-5, 16-17, and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ni in view of Schwartz as applied to claims 1, 3, 6, 7, 15, 21, and 22 above, and further in view of Hovda et al (US 2003/0208194 A1).

Ni in view of Schwartz discloses the electrode of claims 3 and 22, with the features described above, wherein the hollow electrode and the saline solution pipe are conductive (Ni, column 3 lines 44-46), further comprising a power source (65, Fig 8) for providing RF electricity (column 4 lines 56-58) and which is capable of being configured to apply different power to the hollow electrode and the saline solution pipe in the form of a bipolar configuration; but does not disclose an insulation member formed on the surface of the hollow electrode to prevent short circuiting. Hovda teaches an electrosurgical device comprising an electrode (104, Fig 12A), and a second conducting member (112) which forms an annular gap (54) which defines a fluid path (83) for a conducting liquid (50, paragraph 0103); an insulation member formed on the surface of the electrode (78) which would prevent short circuit of the saline solution supplied through the gap between the electrode and the saline solution pipe; and an insulation packing (102) provided between the electrode and the saline solution pipe (Fig 12A). It would have been obvious to one of ordinary skill in the art at the time the invention was

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made to have modified the invention as disclosed by Ni in view of Schwartz by including the saline solution pipe and insulation member as taught by Hovda in order to ablate desired tissue in a bipolar configuration and to provide a pathway for electrical current flow between the active and return electrodes.

***Allowable Subject Matter***

Claim 8 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Papapietro whose telephone number is (571) 272-1546. The examiner can normally be reached on M-F 9am-5:30pm.

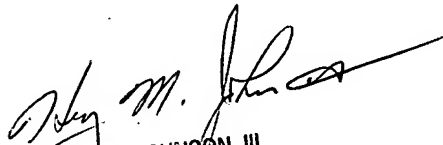
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JMP

Jacqueline Papapietro  
Art Unit 3739

  
HENRY M. JOHNSON, III  
PRIMARY EXAMINER